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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/696,909 | 10/29/2003 | James B. Lorens | 021044-005820US | 9257 |

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| EXAMINER | |
|---|---|
| REDDIG, PETER J | |
| ART UNIT | PAPER NUMBER |
| 1642 | |

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/696,909 | LORENS ET AL. | |
| | Examiner | Art Unit | |
| | Peter J. Reddig | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups I-XVIII. Claims 1-18, 27-45, drawn to a method for identifying a compound that modulates angiogenesis comprising contacting the compound with a single one polypeptides selected from the group of 18 angiogenesis polypeptides disclosed in claim 1, classified in class 435, subclass 4. Claim 12 will be examined as it is drawn to the elected group and species. Claims 27-45 will be examined as they are drawn to the elected group and species.

Groups XIX-XXXVI. Claim 19, drawn to a method for identifying a compound that modulates angiogenesis and cell cycle arrest comprising contacting the compound with a single one of the of the polypeptides selected from the group of 18 angiogenesis polypeptides disclosed in claim 19, classified in class 435, subclass 4.

Groups XXXVII-LIV. Claims 20-26 and 46-52, drawn to a method of modulating angiogenesis in a subject, the method comprising administering to the subject a therapeutically effective amount of a single one of the compounds selected from the group of 18 angiogenesis polypeptides

disclosed in claim 1, classified in class 514, subclass 2. Claims 46-52 will be examined as they are drawn to the elected group and species

**The inventions are distinct, each from the other because of the following reasons:**

The inventions are distinct, each from the other because of the following reasons:

1. Inventions of Groups I-XVIII are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are related in that they are methods for identifying a compound that modulates angiogenesis. The inventions are distinct because each angiogenesis polypeptide is a distinct product.

It is the structural differences engendered by differences in the primary amino acid sequence that give each protein its unique function within the cell. It is unlikely that any two proteins, even those that are very homologous, have the exact same structure and function. For example, even single amino acid changes in proto-oncogenes can alter protein structure and function in a way to make them oncogenic. Thus, Groups I-XVIII are distinct inventions.

The search for all of the angiogenesis polypeptides would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all the different sequences encoding

different polypeptides or vice versa would require extensive searching and review in the non-patent and patent literature databases. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Furthermore, searching all of the inventions of Groups I-XVIII would invoke a burdensome search. Although the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

2. Inventions of Groups XIX-XXXVI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method is drawn to identifying a compound that modulates angiogenesis and cell cycle arrest. The inventions are distinct because each angiogenesis polypeptide is a distinct product.

It is the structural differences engendered by differences in the primary amino acid sequence that give each protein its unique function within the cell. It is unlikely that any two proteins, even those that are very homologous, have the exact same structure and function. For example, even single amino acid changes in proto-oncogenes can alter protein structure and function in a way to make them oncogenic. Thus, Groups XIX-XXXVI are distinct inventions.

The search for all of the angiogenesis polypeptides would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all the different sequences encoding different polypeptides or vice versa would require extensive searching and review in the non-patent and patent literature databases. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Furthermore, searching all of the inventions of Groups XIX-XXXVI would invoke a burdensome search. Although the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

3. Inventions of Groups XXXVII-LIV are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method is drawn to a method of modulating angiogenesis in a subject, the method comprising administering to the subject a therapeutically effective amount of a single one of the compounds selected from the group of 18

angiogenesis polypeptides disclosed in claim 1. The inventions are distinct because each angiogenesis polypeptide is a distinct product.

It is the structural differences engendered by differences in the primary amino acid sequence that give each protein its unique function within the cell. It is unlikely that any two proteins, even those that are very homologous, have the exact same structure and function. For example, even single amino acid changes in proto-oncogenes can alter protein structure and function in a way to make them oncogenic. Thus, Groups XXXVII-LIV are distinct inventions.

The search for all of the angiogenesis polypeptides would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all the different sequences encoding different polypeptides or vice versa would require extensive searching and review in the non-patent and patent literature databases. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Furthermore, searching all of the inventions of Groups XXXVII-LIV would invoke a burdensome search. Although the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

4. The restriction of the Groups I-XVIII, Groups XIX-XXXVI, and Groups XXXVII-LIII as independent inventions is proper. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103.

5. The inventions of Groups I-XVIII and Groups XIX-XXXVI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups XIX-XXXVI and Groups XIX-XXXVI are related because they directed to methods of identifying compounds that modulate angiogenesis. The methods Groups XIX-XXXVI and Groups XIX-XXXVI are distinct because Groups XIX-XXXVI has the distinct objective of identifying a compound that modulates cell cycle arrest.

Furthermore, searching all of the inventions of Groups I-XVIII and Groups XIX-XXXVI would invoke a burdensome search. Although the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search

involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

6. The inventions of Groups I-XXXVI and Groups XXXVII-LIV are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-XXXVI and Groups XXXVII-LIV are related because they directed to methods of angiogenesis regulation. The methods Groups I-XXXVI and Groups XXXVII-LIV are distinct because Groups XXXVII-LIV has the distinct objective of modulating angiogenesis in a subject and the distinct steps of administering angiogenesis modulating compounds to that subject.

Furthermore, searching all of the claims of Groups I-XXXVI and Groups XXXVII-LIV would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

Because, these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

**7. Species Elections for Groups I-LIV**

A. Claims 1-18 and 27-44 are generic to the following patentably distinct species for the location for identification of a compound that modulates angiogenesis.

1. *in vivo* as contemplated in the specification

2. *in vitro* as contemplated in the specification and claimed.

B. Claims 3, 5, 7, 9, 19, 29, 31, 33, 35, and 45 are generic to the following disclosed patentably distinct species of "functional effect":

1) physical effect

2) chemical effect

3) phenotypic effect

C. Claim 15-18, 22-25, 40-44, and 48-51 are generic to the following disclosed patentably distinct species of "compounds":

1) antibody

2) antisense molecule

3) RNAi

4) small organic molecule

D. Claim 19 is generic to the following disclosed targets for determining the physical effect of a compound.

1) polypeptide or fragment thereof

2) inactive variant of the polypeptide

8. The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of group A, B, C, and D. even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

PJR